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APPLICATION NUMBER:

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CLINICAL REVIEW(S)

CLINICAL REVIEW

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Division / Office Division of Psychiatry
Products/ODE 1

Reviewer Name(s) Nancy Dickinson, PharmD.
Review Completion Date 5/19/17

Established Name Mixed salts of a single-entity
amphetamine
(Proposed) Trade Name Mydayis
Therapeutic Class stimulant
Applicant Shire

Formulation(s) Extended release capsule
Dosing Regimen Once daily in morning
Indication(s) Attention deficit hyperactivity
disorder (ADHD)
Intended Population(s) Adults, pediatrics (b) (4) years

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Nancy Dickinson, PharmD.
NDA 022063
Mydayis (mixed salts of a single-entity amphetamine extended release capsule)

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